(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 March 2004 (11.03.2004)

PCT

(10) International Publication Number
WO 2004/019758 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number:
PCT/US2003/026388

(22) International Filing Date: 21 August 2003 (21.08.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/406,515 27 August 2002 (27.08.2002) US

(71) Applicant *(for all designated States except US)*: INTERMUNE, INC. [US/US]; 3280 Bayshore Boulevard, Brisbane, CA 94010-1317 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: CRAGER, Michael [US/US]; 63 Lorelei Lane, Menlo Park, CA 94025 (US). HARKONEN, Scott [US/US]; 125 Montalvo Avenue, San Francisco, CA 94116 (US). .

(74) Agent: BORDEN, Paula A.; Bozicevic, Field & Francis LLP, 200 Middlefield Road, Suite 200, Menlo Park, CA 94025 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: METHODS OF TREATING IDIOPATHIC PULMONARY FIBROSIS

InterMune, Inc.
Protocol GIPF-001: Subcutaneous IFN-γ for Idiopathic Pulmonary Fibrosis

Table 19.3.1

Cumulative Probability of Survival^ - Kaplan-Meier Estimates (Standard Errors)
Baseline FVC ≥ Predicted: < 55
Intent-to-Treat

Week	IFN-γ 1b (N = 36)	Placebo (N = 40)	P-Value*
Week 12	0.92 (0.046)	0.98 (0.025)	
Week 24	0.89 (0.052)	0.90 (0.047)	
Week 36	0.83 (0.063)	0.88 (0.052)	
Week 48	0.75 (0.073)	0.83 (0.061)	
Week 60	0.75 (0.073)	0.83 (0.061)	
Week 72	0.68 (0.090)	0.83 (0.061)	
Week 84	0.68 (0.090)	0.83 (0.061)	0.434
Time to Survival (Days)‡ 75th Percentile	318.0	-	
Number (%) of Survivors	26 (72.2%)	33 (82.5%)	

^ Distribution of time to the occurrence of death.
‡ Time to Survival (Days) = Date of death - Date of randomization +1.
For patients who survive as of 6/26/2002 the time to survival was considered a censored observation.
Days = June 26 2002 - Date of randomization +1.
* Test for treatment effect using log rank test stratified by smoking status.

(57) Abstract: The present invention provides methods of treating idiopathic pulmonary fibrosis (IPF); methods of increasing survival time in an individual with IPF; and methods of reducing risk of death in an individual with IPF. The methods generally involve administering a therapeutically effective amount of IFN-γ to an individual with IPF.

WO 2004/019758 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.